

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-3-2007 has been entered.

The amendment filed on 4-4-2008 is acknowledged. Claim 1 has been amended.

### ***Election/Restrictions***

Applicant argues that withdrawn claim 9 should be examined with elected claims 1 and 2 as all of said claims require the detection of OprF and that claim 9 properly narrows independent claim 1. Applicant's arguments have been fully considered and deemed non-persuasive. Contrary to Applicant's assertion, claim 9 requires the measurement of OprF expression levels in multiple samples over multiple time points which is vastly different than merely detecting the presence of OprF in a single sample.

Consequently, claims 1-10 are pending. Claims 3-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1 and 2 are currently under examination.

### ***Drawings***

The objection to the drawings filed on 10-20-2003 is maintained for reasons of record. Applicant's submission of a replacement for Figure 4 on 1-4-2007 is acknowledged and said drawing is deemed acceptable. However Applicant has failed to address the deficiencies in Figures 1-3 and 5-6. The reproductions of gels in these figures are still of such poor quality they were unreadable. New corrected drawings are required in this application because due to the errors outlined above. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Rejections Withdrawn***

The rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the amendment thereto.

The rejection of claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of detecting a *Pseudomonas aeruginosa* infection by the detection of its porin F protein (OprF), does not reasonably provide enablement for methods for assessing cystic fibrosis disease based on the presence or absence of OprF or the determination of whether a mucous lining in a given airway of the individual is anaerobic is withdrawn in light of the amendment thereto and Applicant's assertion (see page 7 of applicant's response), that the presence of OprF is in itself a "determination" of the presence of anaerobic conditions in the mucosal linings of airways.

The new matter rejection of claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, based on the limitation "making a determination of whether a mucous lining in an airway of the

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individual is substantially anaerobic, and (c) assessing the disease of the individual accordingly...” in claim 1 is withdrawn in light Applicant’s assertion (see page 7 of applicant’s response), that the presence of OprF is in itself a “determination” of the presence of anaerobic conditions in the mucosal linings of airways.

The rejection of claim 1-2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the parenthetical use of the term “OprF” in claim 1 is withdrawn in light of the amendment thereto.

The rejection of claim 1-2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the parenthetical use of the term “substantially anaerobic” in claim 1 is withdrawn in light of the amendment thereto.

### ***Claim Rejections Maintained***

#### ***35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 1 and 2 as rendered vague and indefinite by the use of the phrase “assessing the disease of the individual accordingly” is maintained for reasons of record.

#### **Applicant argues:**

1. The term “assessment” is explicitly defined in the specification on pages 12-13.

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2. All examples are underpinned by the teaching that such a determination is indicative of a progression of the disease toward chronic status.
3. Figure 5 compares the serum from various patient types such that prognosis, monitoring and intervening may be indicated in accordance.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the cited definition is based solely on the presence or absence on of OprF or OprF antibodies whereas the "assessment" step is based not only on the presence or absence of OprF but also determining whether the mucosal lining of an airway is anaerobic. Consequently, said definition does not address the instant method.

With regard to Points 2 and 3, it is impossible to determine the disease state based solely on a single time point. Treatment efficacy, disease stage and disease progression require a comparison of multiple time points to a baseline. Moreover, it is still unclear what "active step" is performed in determining the anaerobicity of a given mucosal lining.

As outlined previously, it is unclear on what said "assessment" is based. What are the criteria utilized? How is the result of the "determination" of step (b) utilized? As written, it is impossible to determine the metes and bounds of the claimed invention.

### ***Reinstated Claim Rejections***

#### ***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mutharia et al.

(Infection and Immunity, 1983, Vol. 42 No. 3, pages 1027-1033).

Mutharia et al. disclose measuring OprF in *Pseudomonas aeruginosa* isolates from CF patients (see abstract and page 1029). As attested to by Applicant (see page 7 of applicant's response), the presence of OprF is in itself a "determination "of the presence of anaerobic conditions in the mucosal linings of airways. Consequently, Mutharia et al. anticipates all the limitations of the instant claims.

### ***35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Mutharia et al. (Infection and Immunity, 1983, Vol. 42 No. 3, pages 1027-1033).

Mutharia et al. disclose measuring OprF in *Pseudomonas aeruginosa* isolates from CF patients (see abstract and page 1029).

Mutharia et al. differs from the instant invention in that they do explicitly disclose the direct testing of surface liquid, sputa or combinations thereof.

Since Mutharia et al. disclose that OprF levels can be detected in *Pseudomonas aeruginosa* from CF patients, it would have been obvious for one of ordinary skill in the art to use the detection of OprF in biological samples to determine whether a given CF patient had a *Pseudomonas aeruginosa* infection. Moreover, as attested to by Applicant (see page 7 of applicant's response), that the presence of OprF is in itself a "determination" of the presence of anaerobic conditions in the mucosal linings of airways.

One would have had a reasonable expectation of success as Mutharia et al. disclose that OprF was present on *Pseudomonas aeruginosa* from CF patients.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Robert A. Zeman/  
Primary Examiner, Art Unit 1645  
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